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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,902	10/05/2001	Peter R. Oeltgen	ZYM/09US	4028

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/971,902	OELTGEN ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of Applicant's amendment and arguments filed on 15 December 2003, is acknowledged. Claims 1, 8 and 10 have been amended and new claim 12 has been added. Thus claims 1-12 are pending and under consideration.

2. The following previous objection is withdrawn in light of Applicants amendments filed on 12/15/03:

2a. The objection of claims 1-11 is withdrawn.

2b. The rejection of claims 1-11 made under 35 U.S.C. 112, second paragraph, is withdrawn.

Response to Applicants' Arguments and Amendment:

Claim Rejections - 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. The rejection of claims 1-11, made under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained for reasons of record, set forth in the office actions mailed on 08 April 2003 and 16 September 2003. The new claim 12 is also rejected under this statute for the same reasons.

Applicants argue that the additional information discussed by the Examiner is not required to enable the instant claims. Applicants argue that since the claims are not drawn to the peptide's mechanisms of action, one need not to know the pharmacological or biochemical processes involved to know that the method achieves a

therapeutics response. Applicants contend that the claimed method of decreasing or treating hepatic injury is assessed as effective by routine clinical chemistry values for hepatic function, which are known to one skilled in the art. Applicants submit that realization of the claimed treatment is determined by a routine serum chemistry panel, whereby the hepatic function parameters return to normal and are maintained at normal values. Applicants further argue that that the Examiner's assertion that it is undue experimentation to determine which specific cytokines are affected by the peptide of SEQ ID NO:1 and how they are affected is not within the scope of the claims. Furthermore, Applicants argue that controls to determine side effects of the Applicant's method are not required.

These arguments have been fully considered but are not found persuasive. With respect to Applicants' first argument, although the instant claims are drawn to a method of decreasing or treating cytokine mediated hepatic injury, instant specification does not disclose one single case where cytokine mediated hepatic injury was decreased or treated. Instant specification does not demonstrate or show that administering peptide of SEQ ID NO:1 to a mammal achieves the desired therapeutic response, it merely asserts that it does. The Examiner is not asking that Applicants disclose the mechanism of action of the peptide of SEQ ID NO:1, but that instant specification should disclose more than just mere prophetic statements that the peptide of SEQ ID NO:1 decreases or treats cytokine mediated hepatic injury, by the administration of the peptide of SEQ ID NO:1. Applicants are correct in that on page 4, the specification states that hepatic injury can be determined by elevated levels of

hepatic enzymes, and discloses what is the range of normal serum levels of some of these enzymes. Applicants are also correct in that a simple serum analysis reveals whether hepatic enzymes are elevated. However, the specification does not disclose any data regarding the administration of the peptide of SEQ ID NO:1 and levels of these hepatic enzymes. Should the skilled artisan assume that simply administering the peptide of SEQ ID NO:1 would bring all these hepatic enzyme down to normal levels? The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue experimentation. In the instant case, the amount of experimentation to delineate whether peptide of SEQ ID NO:1 is effective against hepatic injury, is undue, and there is no guidance provided by Applicants. Furthermore, the specification provides no reason as to why the peptide of SEQ ID NO:1 would be effective in treating hepatic injury, and prior art is silent on the issue. Therefore, the skilled artisan would not predict that the administration of the peptide of SEQ ID NO:1, would decrease or treat hepatic injury, and instant specification does not provide any data that supports said assertion. Although working examples are not required under 35 U.S.C §112, first paragraph, they are one of the factors that must be considered when determining enablement, especially in light of the lack of guidance in

the specification and the nature of the invention, since prior art is relatively silent to the instantly claimed method of treating hepatic injury or decreasing cytokine mediated hepatic injury response by administering the peptide of SEQ ID NO:1. Applicants provide no sound scientific reasoning as to why the peptide of SEQ ID NO:1, would be expected to treat hepatic injury. Contrary to Applicants' argument, proper controls addressing whether there are any undesirable side effects, are necessary in order to avoid detrimental outcome, since the claimed method is suppose to benefit the mammal.

Although Applicants recite certain dosages and duration of administration, of the peptide of SEQ ID NO:1, to treat or decrease hepatic injury, they provide no evidence that this peptide was ever used *in vivo* or *in vitro*.

Therefore, claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

Conclusion:

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
19 March 2004

Gary L Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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